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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,334	03/09/2000	Ry Wagner	7896-72620-03	3299
74051	7590	02/04/2008	EXAMINER	
Klarquist Sparkman, LLP			KRUSE, DAVID H	
121 SW Salmon St., Floor 16				
Portland, OR 97204			ART UNIT	PAPER NUMBER
			1638	
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			02/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/522,334	WAGNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-10, 16, 17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-10, 16, 17 and 19-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/31/2007.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on October 31 2007 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. Claims 2 and 19 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 May 2007. Applicant's arguments filed 31 October 2007 have been fully considered but they are not persuasive.

Applicants argue that the Office appears to be requiring the same level of written description as would be required if Applicants were claiming the genes themselves, and that this is not, and cannot be, the appropriate standard, as it would make it impossible for any Applicant to ever provide sufficient written description for any screening claim (page 6, 5<sup>th</sup> paragraph of the Remarks). This argument is not found to be persuasive

because the invention of the instant claims require an "isolated gene" (claim 2) "associated with a morphological characteristic" (claim 19) to practice, which are not adequately described.

Applicants argue that they are not claiming all of the individual genes/sequences that have been or can be discovered using Applicants' method, thus the rejection is therefore inappropriately made against the method claims (page 7, 4<sup>th</sup> paragraph of the Remarks). Applicants argue they have provided a sufficient written description for this aspect of the invention, since what is required is adequate written description rather than a recitation of each and every possible species within a genus. Applicants argue they have provided complete and adequate description of "a method of identifying genes associated with a desired trait in a tomato plant" - as evidenced by the Office not rejecting claim 20 along with claims 2 and 19. Having adequately described how to identify, isolate, and characterize "genes the transcription of which was enhanced by said enhancer" using that method (as is accomplished in claim 20), it cannot be possible that those genes are not adequately described for a claim depending therefrom (e.g., claims 2 and 19) (paragraph spanning pages 7-8 of the Remarks). These arguments are not found to be persuasive. A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424, 1433 (DC WNY 2003) which teaches knowing the "starting point" is not enough; that is little more than a research plan. The patent describes how to test compounds to determine whether they work, but it does not set forth any procedure that will necessarily lead to discovery of

such a compound, nor does it even identify any particular class of compounds that contains at least one suitable member. In the instant case Applicants describe a method of identifying tomato genes using a activation tagging process, but do not adequately describe what tomato genes are identified, which are required to practice the invention of the instant claims.

***Claim Rejections - 35 USC § 103***

3. Claims 2-10, 16, 17 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walden *et al* 1994 (Plant Molecular Biology 26:1521-1528) in view of Meissner *et al* (1997 The Plant Journal 12(6): 1465-1472); Sundaresan *et al* (1995 Genes & Development 9: 1797-1810); and Seabrook *et al* (U.S. Patent 6,071,746, filed 2 February 1998). This rejection is modified from the rejection of record as set forth in the last Office action mailed 15 May 2007. Applicant's arguments filed 31 October 2007 have been fully considered but they are not persuasive.

Walden teaches a method of identifying and isolating genes implicated as playing a role in plant growth and development in tobacco comprising transforming plant cells with a plant cell expression vector having an *E. coli* origin of replication, a 4X tandem 35S promoter, a kanamycin selectable marker-encoding nucleotide sequence operably linked to a promoter and a transcription termination element and a T-DNA sequence using an *Agrobacterium* transformation method (see Fig. 1 on page 287).

Walden does not teach said method using a tomato, nor does Walden teach said method using all of the claimed enhancers, an herbicide resistance gene or a dwarf plant.

Meissner *et al* teach using Micro-Tom tomato plants as a model system for tomato genetics to identify genes involved in pigmentation, leaf shape, flowers and fruit (see abstract on page 1465). Meissner *et al* teach using an enhancer trap method taught by Sundaresan *et al* at page 1466, left column, 2<sup>nd</sup> paragraph. Meissner *et al* teach using kanamycin or a chlorsulfuron resistance ALS gene operably attached to a 2X tandem 35S promoter sequence for selecting transformed tomato plants at Figure 3 on page 1468. Meissner *et al* teach using *Agrobacterium* to transform cotyledons at page 1471, left column, 1<sup>st</sup> paragraph.

Seabrook *et al* teach a method of culturing and regenerating tomato plants using hypocotyl explants at column 18. Seabrook *et al* teach that the method can be used for the maintenance, and propagation of transgenic plants following the transformation of a plant with standard transformation protocols like *Agrobacterium* (column 12, lines 23-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Walden *et al*, using the Micro-Tom tomato model system taught by Meissner *et al* in a gene activation tagging method. Meissner *et al* teach that important genes can be isolated (page 1466, left column, 2<sup>nd</sup> paragraph) and that transgenes can be efficiently characterized in tomato (page 1469, right column, 2<sup>nd</sup> paragraph). Meissner *et al* teach that it would have been obvious to identify genes involved in pigmentation, leaf shape, flowers and fruit (see abstract on page 1465). Seabrook *et al* teach that using a hypocotyl explant would have been an obvious choice in a method of tomato transformation. Given that fact that

Walden *et al* teach that activation tagging in tobacco (a Solanaceous plant) one of ordinary skill in the art at the time of Applicants' invention would have had a reasonable expectation of success in using tomato (a Solanaceous plant). In reference to the listed enhancers in claims 3-7, the use of a dwarf plant or a dwarf tomato plant at claims 11 and 23, and the specific transformation methods for tomato cited in claims 21 and 22, the following arguments are put forth. Applicant admits that enhancers of gene transcription, in particular promoters, were well known in the art at the time of Applicant's invention, that would operate in tomato, for example (see page 13 of the specification). In addition, the specific transformation methods for tomato cited in claims 21 and 22 do not appear to be critical features of the claimed invention (see Seabrook *et al*), in fact Applicant teaches using a leaf transformation method at page 22 of the specification, and methods well known in the art at the time of Applicant's invention for transforming tomato. Hence it is unclear from the instant specification where the examples of unexpected results are taught in relation to the instant claims. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Applicants argues that even if one were to assume that Walden *et al.* teaches a plant transformation vector that encompasses all elements of Applicants' vector (part (i) of claim 20), neither Walden *et al.*, Jones *et al.*, or a combination of these two references includes all of the method steps required by that claim (page 12, 3<sup>rd</sup>

paragraph of the Remarks). This argument has been addressed in the instant modified rejection.

Applicants argues that Walden teaches exclusively a directed screen that will, at best, only result in the identification of transformed plant cells (*in vitro*) that have a desired characteristic that is pre-selected prior to the start of the screen. Applicants argues that their (Walden) described method will miss any and all insertional events that implicate a phenotype other than the one they are specifically selecting for (that is, they teach only focusing on a single "desired trait" at a time, to the exclusion of all others), as well as any and all insertional events the effects of which can only be perceived in a whole plant or plant tissue. Applicants argues that there is no teaching whatsoever of a method of "selecting plants having a desired trait" which trait is caused by transcriptional enhancement mediated by the "enhancer" in the plant transformation vector - as required by Applicants' claims. Applicants argues that since Jones *et al.* does not teach any method that is capable of identifying a trait that is caused by such transcriptional enhancement (since Jones *et al.* does not teach use of an enhancer element in a transformation vector), neither of the cited references alone or in combination teach this element of Applicants' claimed invention (paragraph spanning pages 12-13 of the Remarks). These arguments have been addressed in the instant modified rejection, specifically the teachings of Meissner *et al.*

Applicants argues that the steps of "regenerating transformed plant cells [that were selected using the "selective agent that is toxic to non-transformed plant cells"] to yield mature plants" and then "selecting plants having a desired trait..." are explicitly

recited in the claims. Applicants argues that these steps are not provided by either of the cited references, nor would they be considered by one of ordinary skill in the art as obvious extensions of the teachings of the references, for this reason alone, the rejection under § 103 cannot and should not be maintained. These arguments have been addressed in the instant modified rejection. Meissner *et al* teach using a selective agent, chlorosulfuron or kanamycin. Meissner *et al* also teach selecting plants having a desired trait as outlined above.

***Conclusion***

4. The rejection under 35 USC 102(b) of record is withdrawn in view of Applicants' amendments.
5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

**DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER**



David H. Kruse, Ph.D.  
31 January 2008

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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